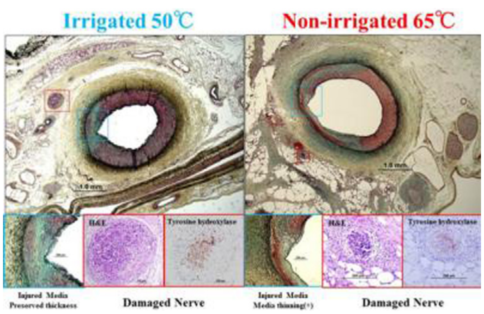
Results: A total of 690 sections from 20 RAs were histologically examined. Arterial media injury was significantly less in the irrigated 50°C group (depth; 3.1[2.5-3.5], circ; 1.1[0.8-1.4], thinning; 32%) compared to the non-irrigated 65°C (depth; 3.5[3.1-4], circ; 1.9[1.5-2.4], thinning; 79%) and 90°C groups (depth; 4[3.5-4], circ; 3.4[2.7-3.8], thinning; 90%) (depth; P=0.04, circ; P<0.001, thinning; P=0.01). Denatured collagen was rarely observed in the irrigated 50°C group (7%) compared to the non-irrigated 65°C (47%) and 90°C groups (91%) (P=0.001). Nerve damage was similar between the irrigated 50°C group (2.5 [2.1 to 3.2]) and 65°C group (2.8 [2.6 to 2.9]) (P=1.00).



Conclusions: Irrigation during RF ablation significantly reduces arterial and peri-arterial tissue injury, while effectively injuring the autonomic nerves.

TCT-490

Evaluation of Acute, Sub-acute, and Chronic Renal Artery Nerve Morphological Changes Following Bipolar Radiofrequency Renal Denervation Treatment in the Porcine Model

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Background: Catheter-based percutaneous renal denervation has shown durable blood pressure reductions in adult patients with resistant hypertension. The objective of this study was to evaluate long-term changes in renal artery nerve morphology induced by bipolar radiofrequency (RF) energy.
Methods: The Vessix System (Boston Scientific, Natick, MA) was used for the renal denervation procedures. The system consists of a RF generator and a low-pressure balloon catheter with an exterior array of bipolar RF electrodes mounted in an offset helical pattern. Juvenile Yorkshire swine (N=17) were treated bilaterally. Renal artery nerves affected by RF treatment were evaluated at 14, 28, and 180 days post-treatment using histopathologic methods to assess quantity, size, and morphological changes.
Results: At 14 days, susceptible nerves (nerves within the RF treatment zone) exhibited primarily degenerative changes (eg, vacuolization, hypercellularity, inflammatory infiltrates, hemorrhage), while at 28 and 180 days, susceptible nerves exhibited chronic changes (eg, intra/peri-fascicular fibrosis, axonal loss, nerve/fascicular atrophy). The average total number of nerves per plane of treated arterial segment was significantly increased at 180 days relative to 14 and 28 days, while the average number of susceptible nerves per plane remained relatively constant over time. The percentage of susceptible nerves was significantly reduced at 180 days relative to 14 and 28 days. The percentage of small nerves steadily increased over time with a concomitant decrease in the number of large nerves.
Conclusions: Bipolar RF energy has an acute injurious effect (degeneration, necrosis) on the renal artery nerves, which progresses to a chronic reactive phase by 28 days post-renal denervation and which is evident for up to 6 months post-treatment. Although the cause for the apparent increase in total nerves and decrease in average nerve size over time is uncertain, these results could potentially reflect the plasticity of nerve growth associated with increased age and size of the animals, or compensatory efforts at target (ie, renal) re-innervation (eg, collateral sprouting).

TCT-491

Renal Artery Denervation with a New Simultaneous Multielectrode Catheter for Treatment of Resistant Hypertension: Results from the Symplicity Spyral™ First-in-Man Study

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Background: Renal denervation (RDN) with the Symplicity Flex™ catheter significantly reduces blood pressure (BP) in patients with treatment-resistant hypertension. A new, multielectrode catheter designed to deliver radiofrequency energy simultaneously to 4 treatment sites was designed to reduce treatment time and resource use while providing a safe and effective denervation procedure. The Spyral™ multielectrode renal denervation system features a unipolar array of 4 electrodes mounted on a nitinol shaft in a spiral configuration and deliver radiofrequency energy (1 minute per artery) in a controlled configuration.
Methods: This prospective, non-randomized, open label, first in man feasibility study will enroll 50 patients. The primary safety endpoint is acute procedure safety associated with the delivery and/or use of the Spyral catheter. The primary effectiveness endpoint is change in office BP from baseline to six months. Included subjects must have resistant hypertension defined as an office systolic BP of ≥160 mm Hg (≥ 150 mmHg for type 2 diabetics) despite adherence to an antihypertensive regimen of at least 3 drugs (preferably including a diuretic). Exclusion criteria include type 1 diabetes, renal artery stenosis >50% or renal artery aneurysm, prior renal artery intervention, or an estimated glomerular filtration rate of < 45mL/min/1.73m2. Subjects will be followed at 1, 3 and 6 months and yearly to 3 years post RDN.
Results: Baseline characteristics for 29 enrolled subjects include age 64 years, 66% male and 41% with diabetes. Baseline BP is 182 ± 16/94 ± 11 mm Hg and the mean number of antihypertensive drugs is 4.7 ± 1.3. The change in office-based BP at 1 month is -16±21/7±12 mm Hg (p<0.001 for systolic BP, p=0.002 for diastolic BP). The total RDN procedure time was 21.2 ±7.7 minutes. There were 2 femoral artery pseudoaneurysms. No new renal artery stenosis or hypertensive emergencies occurred.
Conclusions: RDN using the Spyral™ multielectrode catheter can be safely delivered with a procedure time less than half that of the Symplicity Flex catheter. Further procedural details and 3 month follow-up will be presented.

TCT-492

Renal sympathetic denervation: Does reduction of left ventricular mass translate into improved intramyocardial perfusion?

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Background: Left ventricular (LV) hypertrophy is a common finding in patients with resistant hypertension and is associated with an impaired intramyocardial perfusion. Renal sympathetic denervation (RDN) has been shown to reduce blood pressure (BP) and sympathetic tone. In this pilot study we aimed to investigate the effect of RDN on LV wall thickness, myocardial function, and myocardial perfusion reserve at cardiac magnetic resonance imaging (cMRI) in patients with resistant hypertension.
Methods: Resistant hypertension was defined as mean systolic 24h BP > 145 mmHg despite the use of at least 3 antihypertensive drugs. Adenosin-stress-induced cMRI was performed at baseline, 3, and 6 months after RDN. RDN was performed bilaterally in the renal arteries using a single soft tip radiofrequency catheter (Symplicity, Medtronic, U.S.).
Results: Six patients (5 males, 65±9 years) suffering from resistant hypertension, despite the use of 5±1 antihypertensive drugs, were investigated. Resting systolic BP significantly decreased from 152±9 mmHg to 133±4 mmHg (p=0.02), diastolic BP from 80±4 mmHg to 74±6 mmHg (p=0.04) at 6 months follow-up (FU). LV septal wall thickness was significantly reduced (basal 11.40 to 10.78 mm; p=0.02, midseptal 9.03 to 8.75 mm; p=0.03 and apical 5.87 to 5.28 mm; p=0.03). No significant changes were found for LV ejection fraction and myocardial perfusion reserve index at 6 months FU (Table).

	Pre RSD	6 months FU	p-value
BP systolic (mmHg)	152 ± 9	133 ± 4	0.02
BP diastolic (mmHg)	80 ± 5	74 ± 6	0.04
Ejection fraction (%)	69.2 ± 9	69.6 ± 9	0.68
MPRI*	1.73	1.82	0.70
Septum basal (mm)	11.40	10.78	0.02
Septum mid (mm)	9.03	8.75	0.03
Septum apical (mm)	5.87	5.27	0.03

*myocardial perfusion reserve index

Conclusions: RDN significantly reduced LV septal wall thickness as diagnosed by cMRI, as well as systolic and diastolic BP. However, our pilot data do not show a significant change of the myocardial perfusion reserve. 6 months follow-up might have been too short to lead to significant changes in intramyocardial perfusion of patients after RDN.